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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1995

MEDTRONIC, INC.,

Petitioner,

v.

LORA LOHR, *et vir*,

Respondent, and
Cross Petitioner.

On Writ of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit

MOTION FOR LEAVE TO FILE A BRIEF AND BRIEF FOR TWO PRODUCTS LIABILITY LAW PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF NEITHER PARTY

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March 11, 1996

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The undersigned respectfully move for leave to file the attached brief *amicus curiae* in support of neither party. Counsel for Respondent Lora Lohr consented to the filing of this brief, but Counsel for Petitioner Medtronic did not.[1]

The undersigned teach and write in the area of tort law and products liability and are especially interested in the rapidly accelerating use of federal preemption as a defense.[2]

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[1] At the time that this motion and brief were finalized for printing, counsel for Medtronic represented to the undersigned that he still had not received final instructions from his client in response to our request of January 29, 1996.

[2] *E.g., Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 Wm. & Mary L. Rev. 903 (1996).

The attached brief offers an approach that neither Party is likely to elaborate. Medtronic will argue that the preemption provision in the Medical Device Amendments (MDA), 21 U.S.C. § 360k(a), completely insulates manufacturers from products liability claims; Ms. Lohr will argue that the MDA preempts no tort claims, at least not those claims against manufacturers of medical devices subject to premarket clearance. The proposed *amicus* brief suggests a middle position, encouraging the Court to recognize a limited preemption defense to tort claims. Although not consistent with either Party's ideal litigating position, this formulation would be preferable to their opponent's extreme alternative.

In addition, the proposed *amicus* brief addresses some of the broader implications of the instant case. The Court's resolution of these petitions will have immediate and profound repercussions in other products liability litigation.

Respectfully submitted,

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INTEREST OF *AMICI CURIAE*

Amici teach and write in the area of tort law and products liability,[1] and are especially interested in the rapidly accelerating use of federal preemption as a defense.[2]

---

[1] *See, e.g.*, James A. Henderson, Jr., Richard N. Pearson & John A. Siliciano, The Torts Process (4th ed. 1994); Richard N. Pearson, *The Florida Medicaid Third-Party Liability Act*, 46 Fla. L. Rev. 609 (1994).

[2] *See, e.g.*, Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 Wm. & Mary L. Rev. 903 (March 1996); Lars Noah, *Amplification of Federal Preemption in Medical Device Cases*, 49 Food & Drug L.J. 183 (1994).

This case presents an important opportunity to clarify how courts should apply the preemption provisions that appear in a variety of federal safety statutes to tort litigation. The questions presented by the parties broadly ask the Court to determine whether and to what extent federal law preempts tort claims against manufacturers of medical devices. *Amici* have filed this brief to explain some of the notable difficulties that lower courts have encountered when addressing the increasingly popular preemption defense. The Court's resolution of the instant petitions will have significant consequences for numerous products liability cases.

SUMMARY OF ARGUMENT

The courts below correctly recognized some of the difficulties that attend the application of the preemption defense. The district court granted summary judgment for defendant, dismissing all of the plaintiffs' claims against Medtronic, Inc., the manufacturer of the allegedly defective pacemaker implanted in Ms. Lohr. The United States Court of Appeals for the Eleventh Circuit accepted Medtronic's primary argument that the Medical Device Amendments (MDA)[3] preempted tort claims under Florida state law. Nonetheless, the court reversed judgment with regard to plaintiffs' negligent design and strict liability claims because it held that the Food and Drug Administration (FDA) had not imposed any particular design requirements when it cleared this device for commercial marketing. The Eleventh Circuit, however, affirmed dismissal of the plaintiffs' negligent

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[3] *See* 21 U.S.C. § 360k(a) (1994).

manufacture and failure-to-warn claims, rejecting Ms. Lohr's argument that the preemption defense should not apply insofar as these claims were premised on violations of applicable federal statutory standards. Pet. App. 13a-14a.

As illustrated by the instant case, there are several still unresolved questions concerning the proper application of the preemption defense under the MDA and similar safety statutes. Because the scope of federal preemption turns primarily on matters of statutory construction, the subject defies simple unitary treatment. Indeed, as applied by the courts, the preemption defense lacks any single, coherent meaning. Nonetheless, these statutory provisions pose important recurring problems. *Amici* suggest alternatives to the exaggerated reading of *Cipollone* that has been adopted by a number of courts and was suggested by the Eleventh Circuit in this case. In particular, this Court should clarify that *Cipollone* announced a federal common law rule accepting the "government standards" defense, a defense that would absolve a company of liability only upon a showing of compliance with all relevant safety requirements.

ARGUMENT

Federal preemption arguments in tort actions have proliferated over the last few years. This Court's decision in *Cipollone v. Liggett Group, Inc.*,[4] triggered a notable upsurge in the successful use of preemption as a defense to

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[4] 505 U.S. 504 (1992).

products liability lawsuits. During the decade preceding *Cipollone*, the Court expressed a marked reluctance to find preemption of tort claims,[2] but its decisions from the last several Terms suggest a significant reversal in this attitude.[3] A number of lower courts apparently have viewed *Cipollone* and its progeny as a mandate to dismantle the protections of state tort law, even in extreme situations where a defendant has not complied with the federal requirements that are being given preemptive effect.

Almost four years now have elapsed since *Cipollone* was decided. As feared by a number of the Justices in that case, lower courts have struggled when applying the plurality's judgment in other contexts. Preemption provisions appear in statutes regulating, inter alia, medical devices, pesticides and other hazardous chemicals, and various modes of transportation. Because these provisions express congressional intent in different terms, and in some cases are accompanied by savings clauses of varying breadth, lower courts have encountered difficulties interpreting the proper scope of federal preemption. A number of courts have read *Cipollone* quite expansively, however, finding preemption of most or all tort claims, sometimes even where the defendants have not complied with the applicable federal safety requirements.

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[2] *See, e.g.*, English v. General Elec. Co., 496 U.S. 72, 80-86 (1990); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251-56 (1984).

[3] *See* Freightliner Corp. v. Myrick, 115 S. Ct. 1483, 1487-88 (1995); CSX Transp., Inc. v. Easterwood, 113 S. Ct. 1732, 1740-43 (1993); *Cipollone*, 505 U.S. at 524 (plurality).

Increasingly, defendants assert federal preemption as a defense in tort litigation involving, for example, medical devices and pesticides. This trend represents a departure from the traditional application of preemption as a barrier only to conflicting state and local legislation and regulation, and, more disturbingly, the use of the preemption defense in tort litigation sometimes immunizes defendants from liability irrespective of their conduct. Indeed, as argued herein, lower courts have misinterpreted *Cipollone* by finding broad preemption of tort claims under other federal safety statutes when this Court really had nothing more than the government standards defense in mind.

I. LOWER COURTS HAVE DEVELOPED SEVERAL COMPETING CONCEPTIONS OF PREEMPTION.

Although preemption of tort claims under various statutory provisions generally has been accepted, at least under some circumstances, important questions remain to be resolved. One of the most immediate quandaries concerns the practical consequence of a finding that one or more claims are preempted in a particular case. For instance, does preemption mean that failure-to-warn or other tort claims may never be brought against companies, or instead may a plaintiff sustain such a claim by introducing evidence of noncompliance with agency regulations? If the latter is true, then who bears the burden of proof if noncompliance is alleged; must the defendant prove compliance as a predicate for invoking a preemption defense, or does it become an element of the plaintiff's burden when attempting to assert a claim in the face of such a defense? More fundamentally, is such a defense even properly characterized as one based on "preemption"?

The lower courts have offered varying answers to these questions, suggesting three different conceptions of federal preemption as applied in the context of tort litigation. As more fully developed in the following sections, it is possible to differentiate between a "strong," "intermediate," and "weak" version of the preemption defense based in part on whether compliance with federal safety standards is relevant and which party shoulders the burden of proof on that issue. The choice of one among these competing conceptions of the preemption defense will have profound consequences for litigants in future tort cases.

A. The Strong Version: Preemption as Foreclosing Tort Remedies Altogether.

In the wake of *Cipollone*, several lower courts have suggested that preemption would completely cut off common law claims whenever federal safety requirements apply, whether or not a particular company has strictly complied with those requirements. This view is most noticeable in medical device decisions, including the instant case.[2/]

Under this extreme approach, a plaintiff could not seek compensatory damages for injuries resulting from a manufacturer's failure to abide by federal requirements. Plaintiffs would have no recourse under state tort law, and

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2/ *See, e.g.*, Lohr v. Medtronic, Inc., 56 F.3d 1335, 1343 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (1996); Talbott v. C.R. Bard, Inc., 63 F.3d 25, 27-30 (1st Cir. 1995), *petition for cert. filed*, No. 95-1321 (Feb. 16, 1996); Reeves v. AcroMed Corp., 44 F.3d 300, 307 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); Mendes v. Medtronic, Inc., 18 F.3d 13, 17-19 (1st Cir. 1994); Mears v. Marshall, 905 P.2d 1154, 1166-67 (Or. App. 1995).

courts have consistently rejected arguments that a private right of action exists under any of the federal safety statutes.[8] Similarly, a number of courts have rejected negligence per se claims premised on violations of federal requirements because otherwise, they conclude, plaintiffs could circumvent Congress' intent not to provide a private right of action under these federal statutes.[9]

Under the strong version of preemption, even claims that agency approval was secured by the submission of incomplete or inaccurate data would be unavailable.[10] Courts abiding by the strong version of preemption have squarely rejected the argument that allegations of fraud in procuring approval could defeat an applicable preemption

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[8] *See* Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 810 (1986) (assuming without deciding that Congress intended to prohibit private enforcement of the Food, Drug and Cosmetic Act); Bailey v. Johnson, 48 F.3d 965, 967-68 (6th Cir. 1995); Montauk-Caribbean Airways, Inc. v. Hope, 784 F.2d 91, 97 (2d Cir.), *cert. denied*, 479 U.S. 872 (1986); *In re* "Agent Orange" Prod. Liab. Litig., 635 F.2d 987, 991-92 n.9 (2d Cir. 1980), *cert. denied*, 454 U.S. 1128 (1981).

[9] *See, e.g.*, Miller v. E.I. DuPont de Nemours & Co., 880 F. Supp. 474, 480 (S.D. Miss. 1994); Helms v. Sporicidin Int'l, 871 F. Supp. 837, 839 (E.D.N.C. 1994).

[10] *See, e.g.*, Michael v. Shiley, Inc., 46 F.3d 1316, 1328-29 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); Shots v. CSX Transp., Inc., 38 F.3d 304, 308 (7th Cir. 1994); King v. Collagen Corp., 983 F.2d 1130, 1139-40 (1st Cir.) (Aldrich, J., concurring), *cert. denied*, 114 S. Ct. 84 (1993); Papas v. Upjohn Co., 985 F.2d 516, 519 (11th Cir.) (per curiam), *cert. denied*, 114 S. Ct. 300 (1993).

defense, in part because otherwise such allegations would become routine and difficult to resolve.[11/]

The strong conception of the defense resembles so-called "complete" preemption, a doctrine that has developed under the federal labor statutes. Complete preemption means that the displacement of state law by federal statute is such that a defendant could remove an action from state court under federal question jurisdiction, creating an exception to the well-pleaded complaint rule that would otherwise ignore federal issues raised defensively.[12/] Although the existence of a parallel federal remedy originally was regarded as a prerequisite for complete preemption of a state law claim, such substitution apparently is no longer necessary to support removal.[13/] Courts initially rejected arguments that federal safety statutes establish complete preemption, but several now have granted removal petitions on such a theory.[14/]

[11/] *See Talbott*, 63 F.3d at 29-30; *Michael*, 46 F.3d at 1329; *Reeves*, 44 F.3d at 307; Kemp v. Pfizer, Inc., 835 F. Supp. 1015, 1021-22 (E.D. Mich. 1993); ICI Americas, Inc. v. Banks, 440 S.E.2d 38, 42-43 (Ga. App. 1993), *aff'd in relevant part*, 450 S.E.2d 671 (Ga. 1994).

[12/] *See, e.g.*, Metropolitan Life Ins. Co. v. Taylor, 481 U.S. 58, 63-67 (1987); Franchise Tax Bd. v. Construction Laborers Vacation Trust, 463 U.S. 1, 24-28 (1983).

[13/] *See, e.g.*, Caterpillar Inc. v. Williams, 482 U.S. 386, 391 n.4 (1987); Deford v. Soo Line R.R., 867 F.2d 1080, 1086 (8th Cir.), *cert. denied*, 492 U.S. 927 (1994).

[14/] *See, e.g.*, Shumaker v. C.R. Bard, Inc., 1996 U.S. Dist. LEXIS 822, at *6-9 (D. Mass. Jan. 3, 1996); Richardson v. Advanced Cardiovascular Sys., Inc., 865 F. Supp. 1210, 1213-16 (E.D. La. 1994); Strong v. Telectronics Pacing Sys., Inc., 891 F. Supp. 401, 402-03 (W.D. Mich. 1994). *But see* Hurt v. Dow Chem. Co., 963 F.2d 1142, 1144-45 (8th Cir. 1992)

Similarly, according to some courts, preemption deprives them of subject matter jurisdiction over all tort actions within the preempted domain, apparently in the sense that a federal agency has been given exclusive jurisdiction over the matter.[15] This is similar to the effect of preemption under the National Labor Relations Act. Because Congress assigned exclusive jurisdiction over unfair labor practice claims to the NLRB, federal preemption strips state courts of their subject matter jurisdiction to hear claims of this sort.[16] This Court has emphasized, however, that its decision to vest exclusive jurisdiction in the NLRB "does not apply to pre-emption claims generally but only to those preemption claims that go to the State's actual adjudicatory or regulatory power as opposed to the State's substantive laws."[17] Nonetheless, some state courts have accorded a comparable effect to preemption provisions in federal safety statutes, treating these provisions as divesting them of jurisdiction over tort claims against products or activities that are subject to federal regulation.[18]

Of course, even if not properly regarded as an objection to jurisdiction or a basis for removal, the strong version of

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[15] *See, e.g.*, Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 40 (D. Mass. 1994), *aff'd*, 63 F.3d 25, 29-30 (1st Cir. 1995).

[16] *See* International Longshoremen's Ass'n v. Davis, 476 U.S. 380, 391 (1986).

[17] *Id.* at 391 n.9.

[18] *See, e.g.*, Ryan v. Brunswick Corp., 531 N.W.2d 793, 796 (Mich. App. 1995); Fogal v. Steinfeld, 620 N.Y.S.2d 875, 880 (Sup. Ct. 1994); Little v. Dow Chem. Co., 559 N.Y.S.2d 788, 790 (Sup. Ct. 1990); Mulhern v. Outboard Marine Corp., 432 N.W.2d 130, 134 (Wis. App. 1988).

preemption would support a defendant's motion to dismiss for failure to state a claim, and no set of proffered evidence or amended allegations could save any claims that fall within the preempted domain. Thus, the strong version of the preemption defense effectively forecloses tort remedies altogether.

B. An Intermediate Version: Preemption as Displacing State Tort Law Standards.

Under a less extreme view, federal preemption of tort claims would not completely cut off actions for damages, at least not in the event of noncompliance with federal standards.[19] For example, several courts in earlier medical device cases explained that only the substantive duties imposed under state law are preempted.[20] Under this view, preemption does not foreclose the availability of compensatory damages for personal injuries or other common law remedies, but it does mean that federal regulatory standards will trump tort law standards such as the general duty of care under negligence. Plaintiffs would not be able to invite judges and juries to second-guess, under the guise of

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[19] *See, e.g.*, Lowe v. Sporicidin Int'l, 47 F.3d 124, 130 (4th Cir. 1995); Worm v. American Cyanamid Co., 5 F.3d 744, 748 (4th Cir. 1993); Moss v. Parks Corp., 985 F.2d 736, 740 (4th Cir.), *cert. denied*, 113 S. Ct. 2999 (1993); Jenkins v. James B. Day & Co., 634 N.E.2d 998, 1003-05 (Ohio 1994).

[20] *See, e.g.*, Slater v. Optical Radiation Corp., 961 F.2d 1330, 1334 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992); Hunsaker v. Surgidev Corp., 818 F. Supp. 744, 751 (M.D. Pa. 1992), *aff'd mem.*, 5 F.3d 1489 (3d Cir. 1993); Stewart v. International Playtex, Inc., 672 F. Supp. 907, 910 (D.S.C. 1987); *see also* Rest. (3d) Torts: Prods. Liab. § 7, cmt. e (1995), at 198.

applying a manufacturer's common law duty of care, an agency's safety and utility determinations for products whose design and labeling the agency has either dictated by regulation or individually reviewed and approved.

Because many of the preemption provisions prohibit only "different" state requirements, courts reason that claims premised on noncompliance with the federal standard would not impose a different obligation under state tort law.[21/] The possibility that a company may be liable for violation of federal standards has provided courts with one way of reconciling statutory savings clauses (which preserve existing rights or remedies at common law) with express preemption provisions.[22/] The intermediate version of preemption may, therefore, be understood as nothing more than a choice-of-law principle, directing courts to select federal rather than state standards when resolving tort claims.[23/]

Plaintiffs would be able to recover under state law for injuries in the event that a manufacturer violated the conditions contained in any applicable product license or

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21/ *See, e.g.*, National Bank of Commerce v. Kimberly-Clark Corp., 38 F.3d 988, 993 (8th Cir. 1994); *Moss*, 985 F.2d at 740-41; Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1439 (C.D. Cal. 1994).

22/ *See, e.g.*, Bieneman v. City of Chicago, 864 F.2d 463, 471 (7th Cir. 1988), *cert. denied*, 490 U.S. 1080 (1989); Davis v. Brunswick Corp., 854 F. Supp. 1574, 1581 (N.D. Ga. 1994); Von Anhalt v. Delta Air Lines, Inc., 735 F. Supp. 1030, 1031 (S.D. Fla. 1990).

23/ *See* Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8, 10-12 (1st Cir. 1995); Gonzales v. Surgidev Corp., 899 P.2d 576, 582-83 (N.M. 1995). Although a failure to state a claim objection may be made as late as the trial on the merits, preemption understood merely as a choice-of-law objection would represent an affirmative defense which may be waived if not raised in a timely fashion.

regulation.[24] Indeed, in many jurisdictions, violations of federal requirements constitute negligence per se,[25] though not all jurisdictions recognize this rule.[26] Under the intermediate version of preemption being described here, courts essentially would allow only such negligence per se claims to go forward. Similarly, a fraud-on-the-agency claim might escape federal preemption, assuming it is otherwise available under state law.[27]

Preemption would not, however, depend on proof of compliance with federal standards; instead, a defendant may be found liable only in the event (and only to the extent) that the plaintiff can demonstrate noncompliance with those standards. After all, the argument continues, preemption of positive state enactments does not vary depending on each manufacturer's proof of compliance with federal rules.

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[24] *See* Reiter v. Zimmer, Inc., 830 F. Supp. 199, 204 (S.D.N.Y. 1993); Rinehart v. International Playtex, Inc., 688 F. Supp. 475, 477-78 (S.D. Ind. 1988).

[25] *See, e.g.*, Stanton v. Astra Pharmaceutical Prods., Inc., 718 F.2d 553, 565 (3d Cir. 1983); Lowe v. General Motors Corp., 624 F.2d 1373, 1380 (5th Cir. 1980).

[26] *See, e.g.*, Sheridan v. United States, 969 F.2d 72, 75 (4th Cir. 1992); Swift v. United States, 866 F.2d 507, 508-09 (1st Cir. 1989); Eimers v. Honda Motor Co., 785 F. Supp. 1204, 1208 (W.D. Pa. 1992).

[27] *See Cipollone*, 505 U.S. at 528 (1992) (plurality) (noting that the preemption provision would not foreclose recovery on a fraud claim alleging a failure "to disclose material facts about smoking and health to an administrative agency" if state law created a duty to disclose such information); *id.* at 555 (per Scalia, J.) (conceding that "the hypothetical law requiring disclosure to a state regulatory agency would seem to survive" even a sweeping interpretation of the preemption provision). Since the other Justices would have found no claims preempted, *id.* at 543 (per Blackmun, J.), the Court was unanimous in this regard.

Instead, plaintiffs attempting to sustain claims affected by this type of preemption would have to prove any alleged failures to comply with federal requirements. Thus, rather than supporting either an objection to subject matter jurisdiction or a removal petition, preemption in these cases would be regarded as grounds for either a motion for summary judgment or a motion to dismiss for failure to state a claim if plaintiffs have not alleged any failure to comply.

With the proliferation of more or less detailed (and often ambiguous) regulatory requirements, compliance may be difficult to gauge. Questions of compliance with the statutory labeling requirements for cigarettes can be resolved with relative ease, but efforts to determine whether a medical device manufacturer has fully complied with the requirements found in a premarket approval and any generally applicable FDA regulations could present serious difficulties. The matter would, of course, be simplified greatly if an agency successfully had prosecuted the defendant for a regulatory infraction.[28] Although less clearly probative of noncompliance, formal citations alleging a violation also may support a negligence per se claim. At the other extreme, a plaintiff may argue that the defendant has failed to comply with an applicable regulation notwithstanding the agency's apparent acquiescence. In some situations, courts should

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[28] *See, e.g.*, Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 47 (D. Mass. 1994) (noting, however, that some ambiguity remained over the precise infractions to which the manufacturer had pled guilty), *aff'd*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed*, No. 95-1321 (Feb. 16, 1996).

experience little difficulty resolving such questions, but often the inquiry will be quite complicated.[29]

Because of such difficulties, courts generally recognize that agencies should exercise primary jurisdiction over regulatory matters within their special expertise.[30] Indeed, this is one of the premises underlying the strong version of preemption discussed in the previous section. Short of avoiding the compliance issue altogether through complete preemption, however, courts might differentiate between situations where a regulatory infraction is apparent, as when the agency undertakes enforcement action, and other cases where plaintiff has only alleged some failure to comply with an ambiguous requirement. In any case, under the intermediate version of the preemption defense, claims premised on noncompliance would provide plaintiffs with their sole avenue for relief.

C. The Weak Version: Proof of Compliance as a Predicate for the Defense.

Under the weakest version of preemption suggested by courts in the wake of *Cipollone*, defendants would shoulder the burden of proving compliance as a predicate for

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[29] *See, e.g.*, Lowe v. Sporicidin Int'l, 47 F.3d 124, 130 (4th Cir. 1995); Bammerlin v. Navistar Int'l Transp. Corp., 30 F.3d 898, 900 (7th Cir. 1994); Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990).

[30] *See, e.g.*, Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 654 (1973).

successfully invoking the preemption defense.[21] This conception of preemption differs from the intermediate version described in the previous section, which only forecloses recovery on tort claims premised on state law duties **other** than the duty to comply with any applicable federal safety standards. Thus, rather than serving either as a subject matter jurisdiction objection or as grounds for dismissal (or summary judgment) for failure to state a claim, preemption would constitute an affirmative defense.

Because the weak version is poorly elaborated in the reported cases, though perhaps *Cipollone* itself is an example, one must summarize it by comparison to the other conceptions of the preemption defense described previously. If compliance is undisputed, the outcome will be indistinguishable from the result under the other two versions identified above. Under both the strong and intermediate versions, the preemption defense is not dependent on proof of compliance. Courts abiding by the intermediate version recognize negligence per se claims, but there would be no colorable basis for pursuing such claims in the event that compliance is undisputed. Similarly, even if the weak version of the defense is predicated on proof of compliance, a defendant would escape potential tort liability where there is no dispute that it complied with the applicable federal requirements.

In the event of a dispute over compliance, however, the weak version differs from the intermediate version by placing the burden of proof on the defendant. Because the intermediate version of preemption does not make the defense hinge on compliance but only preserves negligence

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[21] *See, e.g.*, St. Louis S.W. Ry. v. Malone Freight Lines, 39 F.3d 864, 867 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 1963 (1995).

per se claims, plaintiffs would have to carry the frequently difficult burden of establishing noncompliance if they hope to recover damages for their injuries, and even then recovery may be unavailable if a particular jurisdiction does not recognize negligence per se claims for violations of federal standards as a matter of state law.

Under the weak version, by contrast, preemption does not even come into play until the defendant has proven compliance with federal requirements. In light of the potential complexities posed by questions of compliance, this difference in the allocation of the burden may be quite important. Although the plaintiff still shoulders the burden of proof on the underlying tort claims, the defendant's failure to carry the burden with regard to questions of compliance would entirely remove federal preemption from the case (and perhaps invite a negligence per se claim by the plaintiff). Furthermore, under the weak version of preemption, even if the defendant establishes compliance, plaintiffs may be able to rebut that showing by alleging some relevant fraud on the agency.[32/]

Finally, if noncompliance is fairly apparent, the weak version may differ from the intermediate version in the sense that the federal safety standards completely drop out of sight even if the defendant's noncompliance is only partial. For example, the failure to abide strictly by the FDA's labeling requirements in a premarket approval may expose the device manufacturer to both failure-to-warn and design defect claims even if there is no evidence that the medical device deviated from design specifications in the product license. Under the

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[32/] *See, e.g.*, Hurley v. Lederle Lab., 863 F.2d 1173, 1179-80 (5th Cir. 1988); Butcher v. Robertshaw Controls Co., 550 F. Supp. 692, 694-703 (D. Md. 1981).

intermediate version, by contrast, plaintiffs could pursue only a negligence per se failure-to-warn claim under these circumstances. Second, under the weak version, the defendant's conduct may be judged against a more stringent standard of care in the event of noncompliance, so that even trivial deviations from federal requirements may be regarded as sufficiently extreme departures from the state law standard of reasonable care to support the imposition of punitive damages.[33]

II. PREEMPTION SHOULD BE INTERPRETED AS THE GOVERNMENT STANDARDS DEFENSE.

In the face of such confusion over the proper application of statutory preemption provisions in tort litigation, one might favor the simplicity of a clear statement rule, demanding that Congress specifically enumerate tort claims as preempted before displacing common law remedies.[34] Because the plurality's judgment in *Cipollone* has been fully embraced by the Court, however, a clear statement rule seems unrealistic at this juncture. Alternatively, courts might reconsider implied private rights of action under federal statutes that they have now given sweeping preemp-

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[33] *Cf.* Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 243-44, 258 (1984) (even where violations of federal regulations were at most inconsequential, jury could award punitive damages absent preemption).

[34] *See* Hernandez-Gomez v. Leonardo, 884 P.2d 183, 190 (Ariz. 1994), *vacated sub nom.* Volkswagen of Am., Inc. v. Hernandez-Gomez, 115 S. Ct. 1819 (1995) (remanded for further consideration in light of *Freightliner*); Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1543 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984); *cf.* Atascadero State Hosp. v. Scanlon, 473 U.S. 234, 242 (1985).

tive effect.[35] In a sense, this approach would attempt to fix one arguable error in construing congressional intent--namely, the recent tendency to find express preemption of tort claims notwithstanding congressional silence--with what might well be a second error.[36] Instead, by understanding preemption of tort claims as the government standards defense, the Court could make sense of *Cipollone* without giving it the extreme effect suggested by the strong version of preemption.[37]

Although traditionally compliance with federal safety standards has not protected companies from tort liability, under the strong version of preemption companies are now immunized from liability even if they have violated these standards. Surely this is a remarkable turn of events. Instead, courts should view preemption provisions as nothing more than a decision by Congress to give companies a defense to state tort liability if they have complied with federal safety standards. Of the three different conceptions of preemption that have emerged, *Cipollone* only supports the weak version. Although denoted "preemption," this

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[35] *See, e.g.*, Suter v. Artist M., 112 S. Ct. 1360, 1370 & n.16 (1992); Daily Income Fund, Inc. v. Fox, 464 U.S. 523, 536 (1984); Texas Indus., Inc. v. Radcliff Materials, Inc., 451 U.S. 630, 639 (1981); Cort v. Ash, 422 U.S. 66, 78 (1975).

[36] *See, e.g.*, Mendes v. Medtronic, Inc., 18 F.3d 13, 19 n.4 (1st Cir. 1994); Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); Ginochio v. Surgikos, Inc., 864 F. Supp. 948, 956-57 (N.D. Cal. 1994); Kemp v. Pfizer, Inc., 835 F. Supp. 1015, 1022 & n.5 (E.D. Mich. 1993).

[37] For a more detailed treatment of these and other arguments appearing herein, see Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 Wm. & Mary L. Rev. 903 (March 1996).

version of preemption more closely resembles the government standards or approval defense.

Several aspects of *Cipollone* undergird the weak version of preemption. First, the statutory provision at issue in the case made compliance a predicate for invoking the defense.[38] This element of the preemption provision has received little or no attention, however, in part because the tobacco companies have conscientiously used the mandatory warning statements in their labeling. The statutory provision is entitled "Preemption," but, by demanding compliance as a prerequisite for preemption, the cigarette labeling law more closely resembles other federal statutes adopting a government approval defense.[39] Second, because the statute itself specifies the text of these statements, compliance should be relatively simple to determine. Presumably, in the event of noncompliance, a plaintiff alleging injuries from cigarettes would be free to pursue failure-to-warn and related tort claims on theories other than noncompliance with the federal labeling requirement. Arguably, this weak version is not really preemption at all.

Cipollone certainly cannot support the strong version of preemption, in part because of the plurality's distinction between pre- and post-1969 failure-to-warn claims. If the 1969 amendments were understood as completely preempting failure-to-warn claims, then the provision would foreclose

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[38] *See* 15 U.S.C. § 1334(b) (1994) (preempting the imposition of requirements or prohibitions under state law with respect to cigarettes "labeled in conformity with the provisions of this Act").

[39] For example, the National Childhood Vaccine Injury Act provides a compliance defense against failure-to-warn and manufacturing defect claims. *See* 42 U.S.C. §§ 300aa-22(b), 300aa-23(d) (West Supp. 1995).

any tort actions founded on such claims that are brought after 1969, whether or not some of the defendant's alleged negligence pre-dated enactment of the statute.[49] Instead, of course, the *Cipollone* plurality distinguished between claims grounded on *conduct* occurring before and after passage of the preemption provision. Finally, by differentiating among numerous tort claims and only finding preemption of a limited class that was based on a failure to warn, the plurality's decision in *Cipollone* left a number of alternative grounds for recovery available to plaintiffs, so the practical result of preemption was not particularly harsh in that case.

Although preemption provisions in the MDA and other statutes are broader than that applicable to cigarettes, it is not clear that *Cipollone* really dictates the recognition of more sweeping preemption defenses in those cases. None of the other statutes include a similar compliance prerequisite in the text of the preemption provision, and compliance with requirements imposed under those statutes is also harder to determine, but these are reasons for narrowing or distinguishing *Cipollone* rather than unthinkingly giving it even greater effect in other contexts. In particular, the absence of substitute remedies should incline courts against finding preemption of tort law claims unless congressional intent to foreclose such claims is unmistak-

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[49] Although retroactive application of statutes generally is disfavored, see Landgraf v. USI Film Products, 114 S. Ct. 1483, 1496-1504 (1994), complete preemption (operating as a jurisdictional rule, *id.* at 1501-02) would foreclose any claims filed after enactment even if premised on conduct pre-dating the statute. *See, e.g.*, Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc., 959 F.2d 158, 160-61 (10th Cir.) (holding that FIFRA preempted failure-to-warn claims even though defendant's allegedly negligent conduct entirely pre-dated enactment of the preemption provision), *vacated*, 113 S. Ct. 314 (1992), *reinstated*, 981 F.2d 1177, 1178 (10th Cir.), *cert. denied*, 114 S. Ct. 60 (1993).

able.[41] Interpreting preemption provisions as establishing a government standards defense would promote the goal of federal uniformity without foreclosing common law remedies where federal safety standards have been violated.

In a sense, the Court would be recognizing a federal common law defense against state tort claims when a product or activity is subject to regulation under a federal statute that contains a preemption provision. The Court recognized an analogous defense against products liability claims for government contractors supplying military equipment. Like the weak version of preemption, a contractor first would have to identify the government requirements that trigger the defense, then demonstrate compliance with those specifications, and finally not be guilty of fraud or misrepresentation in its dealings with the government.[42] The case for recognizing a government standards defense for compliance with certain federal safety requirements is even stronger than for the contractor defense because the Court can interpret the express preemption provisions in the relevant statutes as more directly justifying the recognition of such a defense as a matter of federal common law. Although the development of federal common law rules generally is reserved for extraordinary circumstances, such interstitial lawmaking is preferable to the tortured feats of statutory construction

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[41] *See, e.g.*, Hodges v. Delta Airlines, Inc., 44 F.3d 334, 338 & n.8 (5th Cir. 1995) (en banc); Abbot v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988); Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1440 (C.D. Cal. 1994). Of course, the plurality in *Cipollone* and the majority in *Easterwood* did not construe the respective statutes so narrowly, but then only the weaker versions of preemption discussed above seem appropriate.

[42] Boyle v. United Technologies Corp., 487 U.S. 500, 512 (1988).

engaged in when lower courts find sweeping express preemption of tort claims.

The theoretical difference between interpreting such provisions as dictating preemption of tort claims or as authorizing courts to fashion a government standards defense may be inconsequential. Even so, courts could decide that a provision preempting state law demonstrates a sufficiently strong interest in uniformity (but not exclusivity) to support application of the government standards defense against tort claims. Whether the defense recognized in *Cipollone* is styled as preemption or government standards, however, this Court should more clearly articulate the prerequisites for invocation of the defense. The three-part government contractor defense suggests one useful formulation that could be readily adapted to this end.

To be sure, significant controversy surrounds the use of the government standards defense. Several justifications are offered in support of its recognition. For instance, allowing recovery of tort damages notwithstanding conscientious adherence to carefully crafted safety standards is both inefficient and unfair, and lay jurors are not qualified to second-guess the safety determinations made by federal regulators. Proponents also argue that the traditional assumptions underlying the hesitancy to accept a government standards defense are open to serious question in light of the radical changes in the regulatory state. The relative strength of these arguments may well vary across different product categories.

Conversely, critics make a number of cogent arguments against the recognition of such a defense to liability. For example, the tort system has the virtue of encouraging product manufacturers to discover and address health and

safety risks before they result in serious injuries, whereas regulators generally can react only after such injuries have come to light. Opponents of the defense also express little or no faith in the reliability of administrative agencies, and they note that government standards may be quite difficult to discern and apply. Finally, of course, the federal government generally offers no direct system of compensation for persons who are injured.

Nonetheless, even critics of the defense should agree that a government standards interpretation of express preemption provisions is far better than the stronger versions of preemption that have been adopted by a number of courts. Furthermore, by deciding that preemption translates into the government standards defense when raised in the context of tort litigation, the Court could decouple the defense and arguments about its desirability from the conceptually different issue of federal preemption of positive state enactments.

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Cipollone was decided under the rubric of federal preemption. Perhaps this was an unfortunate choice of terminology by Congress because it has caused great mischief in other contexts. Before 1992, the Court did not accept preemption as a defense to tort liability, at least not unless the statute provided a substitute remedy or otherwise granted exclusive jurisdiction to a federal agency. The plurality's judgment in *Cipollone*, as refined in a pair of subsequent decisions by this Court, signalled a new willingness to accept preemption as a defense to tort claims.

A number of lower courts have read *Cipollone* and its progeny as an invitation to cut off plaintiffs' access to tort

remedies, even in extreme situations where a company has not complied with the federal requirements that are being given preemptive effect. This strong version of preemption represents the least defensible reading of *Cipollone*. The intermediate version, which does not preempt claims if they are premised on violations of federal requirements, is somewhat more sensible but arguably still more protective than *Cipollone* demands (for instance, where negligence per se claims are not available under state law). Instead, the weak version of preemption, which is really indistinguishable from the government standards defense, is more in keeping with what the Court actually decided in that case. Under this approach, proof of compliance is a predicate for invoking this affirmative defense, and evidence of fraud on the responsible agency could defeat it.

CONCLUSION

For the foregoing reasons, *amici* urge this Court to clarify, in the course of resolving the instant petitions, the limited nature of the preemption defense to tort claims.

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